

Appl. No. : 10/614,648
Filed : July 7, 2003

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REMARKS

Applicants have canceled pending Claims 67-79 without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claim in this or another patent application.

Applicants have added new Claims 93-125. Applicants maintain that the new claims contain no new matter and are fully supported by the specification as filed. Support for the claims can be found, for example, one page 4, lines 27-28; page 5, lines 6-8; page 5, lines 22-27; page 6, lines 8-11; page 8, lines 6-9; page 12, lines 3-10; page 21, lines 21-23; page 21, lines 25-29; page 22, lines 21, line 31-page 22, line 9; page 31, lines 27-30; and elsewhere throughout the specification.

On September 13, 2006, the undersigned and Examiner Lankford conducted a personal interview to discuss the Office Action mailed March 24, 2006 and a proposed claim set. During the interview between the undersigned and Examiner Lankford, the indefiniteness rejections 35 U.S.C. § 112, second paragraph, the written description rejections under 35 U.S.C. § 112, first paragraph, and the rejections under 35 U.S.C. § 103 raised in the Office Action mailed March 24, 2006 were discussed. The undersigned and the Examiner also discussed proposed claim amendments. The undersigned and the Examiner agreed that a proposed claim directed to a composition comprising a first component that comprises an unprocessed adipose tissue obtained from a patient mixed with a second component comprising a concentrated population of cells that comprises adipose stem cells, wherein said concentrated population of cells that comprises adipose stem cells is obtained from said patient would likely overcome the rejections of record.

New Claims 93-125 based on the substance of the interview are now presented for examination on the merits. Applicants respond below to the rejections set forth in the Office Action mailed March 24, 2006. For the reasons set forth below, Applicants respectfully traverse.

Rejection Under 35 U.S.C. § 112, second paragraph - Indefiniteness

The Examiner has rejected Claims 67-79 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the invention. According to the Examiner, the claims recite a composition that appears to be composed of two separate portions,

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but states that the claims do not clearly state how this is accomplished. The Examiner also argues that the recitation of "stem cells" renders the claim unclear, and requests that the claims be amended to clearly define the type of multipotent cells.

Applicants have cancelled Claims 67-79, and maintain that new Claims 93-125 do not raise the same issues that formed the bases of the Examiner's rejection of Claims 67-79. Accordingly, Applicants respectfully request that the indefiniteness rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 112, first paragraph - Written Description

The Examiner has rejected Claims 67-79 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. In particular, the Examiner notes that the rejected claims generically recite "a stem cell," yet maintains that the specification does not demonstrate that Applicants were in possession of the entire scope of "stem cells" encompassed by the claims at the time the application was filed. Further, the Examiner notes that the claims do not recite cells from a specific species of animal, and asserts that Applicants have failed to sufficiently describe a representative number of animals to demonstrate possession of the claimed genus of cells derived from "animals."

Applicants have cancelled Claims 67-79, and maintain that new Claims 93-125 do not raise the same issues that formed the bases of the Examiner's rejection of Claims 67-79. Accordingly, Applicants respectfully request that the written description rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

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Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 67-79 under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over U.S. Patent No. 6,777,231 to Katz et al. ("Katz") or U.S. Patent No. 6,200,606 to Peterson et al. ("Peterson"). According to the Examiner, both Katz and Peterson teach compositions comprising adipose stem cells in a complex mixture substantially free of other cells and tissues. The Examiner also states that the references teach the skilled artisan how and why to purify the desired cells.

Applicants have cancelled Claims 67-79, and maintain that new Claims 93-127 are not obvious over Katz or Peterson, alone or in combination.

Katz describes a preparation of a cell population comprising adipose stem cells mixed with a lipo-derived lattice that is substantially devoid of cells. (*See, e.g., Katz* at Col. 11, lines 21-36). Applicants' claims recite compositions that comprise adipose-derived stem cells combined with unprocessed adipose tissue, wherein the adipose-derived stem cells and adipose tissue are derived from the same patient. Unprocessed adipose tissue contains growth factors, cytokines, and other components including cells. The claimed compositions of adipose-derived stem cells and unprocessed adipose tissue derived from the same patient provide for improved vascularity and increased graft weight when implanted back into the patients, as compared to introduction of adipose tissue alone (*see, e.g., Example 1*), and said compositions provide significant benefits and overcome many of the difficulties encountered with the transfer of adipose-derived stem cells or tissues derived from different patients, such as rejection, inflammation, and the potential of transmission of disease. (*See, Specification* at 3, lines 1-10). Accordingly, Applicants respectfully submit that the new claims are not obvious in light of Katz and withdrawal of the rejections under 35 U.S.C. § 103(a) that are based on this reference is respectfully requested.

Peterson also does not render Claims 93-127 obvious under 35 U.S.C. § 103(a). Peterson describes precursor cells with osteogenic or chondrogenic potential mixed with a suitable carrier including proteins, carbohydrates, synthetic polymers, and the like. (*See, Peterson* at Col. 11, lines 35-52). Peterson also teaches mixing these precursor cells with bioactive compounds such as, cell signaling molecules and growth factors. (*Id.* at Col. 10, line 65-Col. 11, line 1). Peterson also describes mixing precursor cells with collagen. (*See, e.g., Col. 12, line 26; Example 1*).

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Peterson does not teach or suggest mixing concentrated adipose-derived stem cells with unprocessed adipose tissue obtained from the same patient. Accordingly, Applicants respectfully submit that Peterson does not render Claims 93-127 obvious, and Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) in light of Peterson be withdrawn.

Applicants submit that Katz and Peterson alone or in combination do not teach, suggest, or motivate one skilled in the art to make or use the now-claimed invention. Although the cited references describe mixtures of lipo-derived lattice or collagen with preparations that contain adipose stem cells, such mixtures are substantially devoid of cells and many of the factors and components found in unprocessed adipose tissue. Applicants' now claimed invention also requires a mixture of a concentrated cell population that comprises adipose-derived stem cells and unprocessed adipose tissue, wherein the concentrated cell population and adipose tissue are obtained from the same patient. Such compositions alleviate rejection and reduce inflammation and the potential for transmission of disease. Accordingly, Applicants respectfully submit that the now-pending claims are in condition for allowance.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. If the Examiner finds any remaining impediment to the allowance of these claims, the Examiner is respectfully requested to call the undersigned at 619-687-8643 to resolve such issues.

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This action is being filed with a 3-month extension fee. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 22, 2006

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